Department of Veterans Affairs **VHA DIRECTIVE 99-042**
Veterans Health Administration
Washington, DC 20420 **September 21, 1999**

STANDARDIZATION OF GLYCOHEMOGLOBIN TESTING

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes the standards for glycohemoglobin testing and reporting at Department of Veterans Affairs (VA) medical centers.

2. BACKGROUND

a. In 1993, the Diabetes Control and Complication Trial (DCCT) showed conclusively that risk for the development and progression of microvascular and neuropathic complications in patients with type 1 (insulin dependent) diabetes mellitus was directly related to blood glucose control as assessed by serial glycohemoglobin, i.e., hemoglobinA1c (HbA1c) determinations. Based on the DCCT results, the American Diabetes Association (ADA) developed a series of specific blood glucose and glycohemoglobin (GHb) treatment goals for all patients with diabetes. The GHb value has been shown to predict the risk for the development of many of the chronic complications in diabetes. This is analogous to using cholesterol determinations to predict cardiovascular disease. Optimal use of GHb testing requires the standardization of the GHb assays. Without standardization, the reported results between laboratories may not be comparable, even if both laboratories use the same assay method.

b. Under the sponsorship of the ADA and the American Association of Clinical Chemistry, the National Glycohemoglobin Standardization Program (NGSP) was developed. The NGSP tests the methods and equipment of manufactures of GHb assay methods. Manufacturers of GHb assay methods undergo rigorous testing annually to show that their methods provide test results equivalent to the DCCT reference. Manufacturers who meet these standards are awarded the "certificate of traceability to the DCCT reference method." Ordering a glycohemoglobin test from a laboratory that uses an NGSP-certified assay method is the best assurance that the test result can be used as a reliable measure of average blood glucose and risk for the development of chronic complications.

3. POLICY: It is VHA policy that VHA testing for glycohemoglobin will be performed on only those analytical systems that have been certified by the National Glycohemoglobin Standardization Program (NGSP). Laboratories will report on HbA1c values regardless of the analytical system used.

4. ACTION_

a. All testing for glycohemoglobin in VHA medical centers must be performed on analytical systems that have been certified by NGSP. This process ensures that analytical systems from different manufacturers are calibrated to provide results similar to the Diabetes Control and Complication Trial values.

b. Laboratories should report only HbA1c values regardless of the analytical system used.

THIS VHA DIRECTIVE EXPIRES SEPTEMBER 30, 2004

c. Laboratories that are not currently using NGSP certified equipment may continue using their current equipment. At the time the equipment is replaced it must be replaced, with NGSP certified equipment.

d. Laboratories should check the NGSP web site at www.missouri.edu/~diabetes/ngsp.htlm to ensure that the equipment being used for HbA1c is certified by the NGSP.

5. REFERENCES: VHA Clinical Practice Guidelines for the Management of Patients with Diabetes Mellitus.

6. FOLLOW-UP RESPONSIBILITY: Chief Officer, Patient Care Services (11) and the Chief Network Officer (10N) are responsible for the contents of this directive.

7. RESCISIONS: None. This VHA Directive expires September 30, 2004.

S/ Frances M. Murphy, M.D. for
Thomas L. Garthwaite, M.D.
Acting Under Secretary for Health

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